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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,033	06/27/2002	Cristina Alonso-Alija	Le A 33 844	9908

7590 07/15/2003

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EXAMINER

SACKEY, EBENEZER O

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,033	ALONSO-ALIJA ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKKEY	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/20/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-2,5,7,11-13,17-20,22,23,24 in part,25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6,8-10 and 14-16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Oath/Declaration

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Election/Restrictions

1. Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables (e.g. V, T, W, X, Y, A, B, R¹, R² R³ etc) and their widely divergent meanings, a precise listing of inventive groups can not be made. Illustrations of the different inventive concepts may be made by reference to the compounds in the Examples of the instant applications, as for example the compounds of:

Example IIa

Example IV

Example XVIIIb

Example XXb etc.

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In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 is, drawn to method of treating cardiovascular disorders.

Group II, claim(s) 2 is, drawn to method of treating arteriosclerosis, hypertension, venous disorders etc.

Group III, claim(s) 22 is, drawn to method of treating cardiovascular disorders with compounds of formula (I).

Group IV, claim(s) 23 is, drawn to method of treating angina pectoris, ischemia and cardiac insufficiency with compounds of formula (I).

Group V, claim(s) 24 is, drawn to method of treating thromboembolic disorders, arteriosclerosis, venous disorders with compounds of formula (I).

Group VI, claim(s) 25-26 are, drawn to methods of treating fibrotic disorders with compounds of formula (I).

Group VII, claim(s) 27 is, drawn to methods of treating cardiovascular disorders selected from angina pectoris, ischemia and cardiac insufficiency.

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Group VIII, claim(s) 28 is, drawn to methods of treating hepatic fibrosis.

Group IX, claim(s) 3-19 and 21 are, drawn to compounds and composition.

Group X, claim(s) 20 is, drawn to a process of producing compounds of formula (I).

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the treatment of diseases in the various groups are not limited to just the active ingredients of compounds and composition of Group IX. Therefore, they have no special technical feature which is common to Groups I and IX. Additionally, each group of invention is classified in different classes with a plethora of subclasses. Illustrations of the different inventive concepts may be made by reference to the various methods of treating disease state. The compounds of Group IX clearly have different technical features (i.e., the dicarboxylic acid derivative compounds

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of claims 3-19) than that of the methods of using the compounds in treating various disease states such as claim 23. The substituents on the dicarboxylic derivative compounds vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the compounds and process of preparing same imposes a substantial burden on the examination of the claimed subject matter. If applicants elect Group IX, applicants may elect any one of Groups III-VIII which are clearly drawn to different methods for examination.

3. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds and process defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art.

Accordingly, unity of invention is considered to be lacking and a restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

During a telephone conversation with William Gray on 07/03/03 a provisional election was made with traverse to prosecute the invention of

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Group IX, claims 3-19, 21 and species of Example 16, and the method for treating hypertension. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-2, 20, 22, 23, 24 (in part) and 25-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, page 144, the last definition of W "angeordnet ist" appears to be a literal translation or a definition from a foreign language. Correction is required.

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a

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background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 3-4, 6, 8-10, 14-16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosentreter et al. (U.S. Patent Number 5,041,638).

Applicants claim compounds and composition of formula (I) wherein the substituents are as defined, and a method of using said compounds in treating hypertension.

Determination of the scope and content of the prior art (M.P.E.P. §2141.01)

Rosentreter et al. discloses similar compounds and compositions with pharmacological properties for treating leucotriene diseases such as asthma etc., which generically corresponds to the claimed compounds and composition as note the abstract, column 1, lines 16-52, column 3, lines 65-68. The said compounds and compositions are under the genus of

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reference formula (I). See for example when reference variable A and B are carboxyl groups which corresponds with A and B being COOH; reference Y is a direct bond corresponding to T being absent, reference W is CH=CH corresponding to W being CH=CH; reference Z can be O or a direct bond which corresponds to V being O; reference T can be O or a direct bond which corresponds to T being absent; m is 0, each of R², R³ and R⁸ are hydrogen. Additionally, see column 66, Examples 113 and 114 respectively.

Ascertainment of the difference between the prior art and the claims (M.P.E.P. §2141.02)

The instant compounds differ from Rosentreter et al., in that they are close structural analogs of compounds of formula (I), for example in addition to the corresponding definitions above, the overlap of (CH₂)₀ and (CH₂)_n. Rosentreter discloses for example 6-(4-carboxybenzyl)-8-[3-(5-phenoxyphenyl)phenyl]-7(E)-octenoic acid, which is an analogue of formula (I). 6-(4-carboxybenzyl)-8-[3-(5-phenoxyphenyl)phenyl]-7(E)-octenoic acid is

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a subgenus of formula (I) which has been shown to possess pharmaceutical properties. See column 21, lines 36-68 for customary formulations.

Finding of prima facie obviousness---rational and motivation (M.P.E.P. §2142-2143)

One of ordinary skill in the art would be motivated to prepare compounds so closely related to be homologous, isomeric or structural analogs of compounds of the reference so as to be structurally obvious therefrom, or would be rendered obvious by the teachings of the reference in the absence of any unobvious properties especially since one of ordinary skill would expect compounds so closely related structurally to have similar properties. Furthermore, one of ordinary skill would be motivated to use the teachings of Rosentreter et al. to prepare compounds and compositions in the expectation that all compounds and compositions under the genus would be useful for the reference purpose, such as treating various disease state.

Thus, the instantly claimed compounds and compositions would have been suggested to one of ordinary skill absent a showing of unexpected results or properties.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS

July 11, 2003

_____

Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1626, Group 1600